Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL QUALITY MEASURES CLEARINGHOUSE

General

Title

Inpatient perinatal care: the number of live-born neonates less than 2,500 grams that arrive to a Level 2 or higher nursery whose qualifying temperature falls within the criteria for that stratum: cold, very cool, cool, euthermic, and overly warm.

Source(s)

CHIPRA Pediatric Quality Measures Program (PQMP) candidate measure submission form (CPCF): thermal condition of low birthweight neonates admitted to Level 2 or higher nurseries in the first 24 hours of life. Rockville (MD): Collaboration for Advancing Pediatric Quality Measures (CAPQuaM); 42 p.

Measure Domain

Primary Measure Domain

Related Health Care Delivery Measures: User-enrollee Health State

Secondary Measure Domain

Does not apply to this measure

Brief Abstract

Description

This measure divides low birthweight neonates who are admitted to a Level 2 or higher nursery into five strata based upon their admission temperature and calculates the proportion of infants in each stratum based upon their temperature upon arrival to the Level 2 or higher nursery:

Stratum 1 "Cold": All neonates with temperatures less than or equal to 34.5° Celsius
Stratum 2 "Very Cool": All neonates with temperatures greater than 34.5° Celsius and less than or equal to 35.5° Celsius
Stratum 3 "Cool": All neonates with temperatures greater than 35.5° Celsius and less than or equal to 36.5° Celsius
Stratum 4 "Euthermic": All neonates with temperatures greater than 36.5° Celsius and less than or equal to 37.5° Celsius
Stratum 5: "Overly warm": All neonates with temperatures greater than 37.5° Celsius

All temperatures are analyzed using degrees Celsius and reported to one decimal place.

Rationale

This measure addresses a key gap in inpatient perinatal care. Evidence that thermal management (such as hot water bottles and incubators) improves survival of newborn and premature infants exists from as early as the late 19th century (Garrison, 1923; Holt, 1902; Baker, 2000; Pierce, 1875; Currier, 1891; Fischer, 1915; Holt & Macintosh, 1940). Modern studies have confirmed and extended these findings, including potential methods to maintain temperature for infants in the delivery room (Silverman, Fertig, & Berger, 1958; Sinclair, 2007; Watkinson, 2006). Laptook et al confirmed the association of temperature loss with poor outcomes in 5,277 infants, 401 to 1,499 grams, born at any of 15 academic medical centers participating in the National Institute of Child Health and Human Development (NICHD) Neonatal Research Network (Laptook, Salhab, & Bhaskar 2007). A formal item selection process looking at potential measures for infants under 1,500 grams identified neonatal temperature as an independent contributor to a composite quality of care measure (Profit et al., 2011).

Chart review data were collected from three diverse hospitals in New York City. All three hospitals had a range of birthweights and a range of temperatures, both when the developer considered the actual measured temperature and when they adjusted those that were not taken rectally to create a "corrected" core temperature. See Figures 1 and 2 in the original measure documentation.

Temperature predicted in-hospital mortality after controlling for covariates, whether the developer dichotomized at the 35.5° threshold that local physicians proposed or considered each degree of temperature as a continuous variable. Crossing the threshold into hypothermia more than doubled the odds of death, controlling for other variables in the model. The relationship between temperature and survival is monotonic: an increase of each 1° Celsius up to 37° reduced odds of death by more than 35% in the model using a continuous variable (22% for 1° Fahrenheit). Defining hypothermia as admission temperature below 36.0 would estimate an increase in the risk of mortality by 84%, p=0.19.

Risk ratio (RR) is a more informative way to express the results than an odds ratio especially when the underlying risk is large, as in this study (Profit et al., 2011). Regression risk analysis estimates the adjusted risk ratio (ARR) and adjusted risk difference: hypothermia (35.5° C) results in an ARR of 1.48 (95% confidence interval 1.03 to 2.30), indicating a 48% increase in risk, from a baseline risk of 8.9% among those who were euthermic to an exposed risk of 13.1% among those who were hypothermic, controlling for the covariates in the sample. Considering temperature as a continuous variable reveals that increasing the temperature from 34.0 to 35.0 increases the relative chance of survival by 24%, from 35.0 to 36.0 by 26%, and from 36.0 to 37.0 by 27%, resulting in absolute risk reductions of 2.8%, 2.4%, and 2.0% respectively. A core body temperature increase from 34.0 to 37.0 is associated with a relative decrease in mortality of 98% and an absolute decrease in mortality of 7.2%, controlling for other factors in the model. The decrease from 36.0 to 35.5 is associated with a 12% increase in the adjusted mortality risk from 9.4% to 10.5%.

The developer's work confirmed findings in the literature that insurance status and race (Miller, Lee, & Gould, 2011) are associated with outcomes. Anecdotal reports from among the participating hospitals confirm reports in the literature that attention to thermal management can improve temperature outcomes (Billimoria et al., 2013). Refer to the appendix of the original measure documentation for a more complete literature review.

This history, these data, and the absence of currently recommended measures that address adequately this issue all motivate the work of the Mount Sinai Collaboration for Advancing Pediatric Quality Measures (CAPQuaM) to develop a measure of quality of care based upon the temperature upon admission to the neonatal intensive-care unit (NICU).

Evidence for Rationale

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CHIPRA Pediatric Quality Measures Program (PQMP) candidate measure submission form (CPCF): thermal condition of low birthweight neonates admitted to Level 2 or higher nurseries in the first 24 hours of life. Rockville (MD): Collaboration for Advancing Pediatric Quality Measures (CAPQuaM); 42 p.

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Primary Health Components

Inpatient perinatal care; temperature stratification; live-born low birthweight neonates; level 2 or higher nursery

Denominator Description

Live-born neonates with birthweight of less than 2,500 grams admitted to a Level 2 or higher nursery within 24 hours of birth (see the related "Denominator Inclusions/Exclusions" field)

Numerator Description

Live-born neonates with a birthweight of less than 2,500 grams using the first temperature taken in a Level 2 or higher nursery (see the related "Numerator Inclusions/Exclusions" field)

Evidence Supporting the Measure

Type of Evidence Supporting the Criterion of Quality for the Measure

A formal consensus procedure, involving experts in relevant clinical, methodological, public health and organizational sciences

A systematic review of the clinical research literature (e.g., Cochrane Review)

One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

Additional Information Supporting Need for the Measure

Evidence for Importance of the Measure to Medicaid and/or CHIP
In New York State, about half of low birthweight babies are insured by Medicaid. Hypothermia is not only associated with neonatal mortality, but there is evidence that intraventricular hemorrhage (IVH) can also be a consequence of hypothermia. IVH is a significant cause of disability, developmental delay, and, when serious, is a common cause for low birth weight (LBW) infants to develop into children with special health care needs. This has broad impact on Medicaid, Medicaid expenses, and early intervention services, including Early and Periodic Screening, Diagnosis and Treatment (EPSDT) services. Hypothermia, through death and disability, may have a long tail that impacts families and programs associated with Medicaid. Furthermore, the Medicaid population is disproportionately black and in the testing data, black infants were disproportionately hypothermic.

Research Evidence
Key findings from a study of 7,553 neonates (from 61 nurseries) in New York State are the following: temperature was variable within weight categories, and blacks were disproportionately cool compared with Hispanic or non-Hispanic others, who were disproportionately cool compared with non-Hispanic whites, whether or not they were stratified by birthweight category. Deaths were disproportionate among those who were cool, in a graded fashion.

The distribution of mean temperature by nursery ranged from 35.7 to 38.2, with a median of 36.3, a standard error of 0.36, and an interquartile range of 0.4. Twenty-five percent of these nurseries had a mean temperature below 36.1. It is concluded that temperatures do vary across nurseries, further reinforcing the sense that this topic is an important measure of performance.

Evidence for Additional Information Supporting Need for the Measure

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Extent of Measure Testing

Reliability
The basis for the scientific soundness of this measure lies in the use of a hybrid of administrative/encounter and medical records data. Though they have their limitations, these data types have been shown in multiple studies to be a reliable source of information for population level quality measurement. One such study found that quality measures that could be calculated using administrative data showed higher rates of performance than indicated by a review of the medical record alone, and that claims data is more accurate for identifying services with a high likelihood of documentation due to reimbursement.

The key constructs underlying these measures are date and time and temperature.

The developer's feasibility study, designed to determine the ability and ease of collecting related data, showed that date and time are self-evident and that there is mild but manageable variation in how time is reported. This should not impair the calculation of a neonate's age or the relationship of the time of measurement to the time of birth or to the time of arrival to the neonatal intensive-care unit (NICU) as is required in this measure set. The underlying construct for temperature is the core body temperature of the neonate. For neonates of various sizes and gestational age, the optimal approach to measuring the temperature may vary. Measurement approaches that are understood to be valid (articles and specifics of this are in the literature review in the Appendix in the original measure documentation) may include rectal temperatures, axillary temperatures, and when appropriately shielded from a radiant heat source, skin probe temperatures. Research in New York City hospitals found that neonates who were documented to have a rectal temperature were on average about 0.5° Celsius warmer than those for whom the site of temperature was not documented to be rectal. Other studies that are in the literature do not find such a difference, so this may be thought of as an upper bound regarding potential underestimation of core body temperature.

The developer understands that it would be a barrier to the wide adoption of this measure were they to specify changes to institutional standards of care regarding how to measure and record the temperature of low birthweight infants or to establish requirements for measurement given the current evidence in the literature. Therefore they do not offer such specification. Instead they ask that reporting agencies record and share the data regarding how each temperature was assessed so that the agencies receiving the data may use that information should they wish to do so.

The reliability of modern methods for assessing temperature is very high.

Validity
The reliability section above contains some information related to validity as well.

The use of electronically available administrative data in healthcare research and assessment is becoming increasingly common. Most databases contain consistent elements, are available in a timely manner, provide information about large numbers of individuals, and are relatively inexpensive to obtain and use. Validity has been established, and its strengths and weaknesses relative to data abstracted from medical records and obtained via survey have been documented. Administrative data are supported, if not encouraged by federal agencies, including National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), Health Care Financing Administration (HCFA), and the U.S. Department of Veterans Affairs (VA). This measure calls for the use administrative data to identify the universe of low birthweight infants.

The use of Expert Panels has been demonstrated to be useful in measure development and health care evaluation, including for children. Practitioners have been identified as a resource for researchers in developing and revising measures, since they are on the frontlines working with the populations who often become research participants. Involving practitioners can assist researchers in the creation of measures that are appropriate and easily administered.

The validity of this work has benefited from the use of a formal method, a pragmatic adaptation of the

Collaboration for Advancing Pediatric Quality Measures (CAPQuaM) 360° method.

The 360° method is highly engaged with collaborators, partners, and the literature. It seeks to target relevant information and perspective and to have measures emerge from the process. The potential measures are then tested to the extent that time and resources permit. In developing the perinatal measures the developer incorporates:

A high level of engagement with partnered institutions and senior advisors that bring into the process a wide diversity of stakeholders;
A detailed literature review that is updated and supplemented as needed;
Interviews with clinicians;
The CAPQuaM scientific team (professionals qualified in neonatology, pediatrics, obstetrics and gynecology, epidemiology, quality measurement and improvement, patient safety, and public health);
A geographically diverse, multidisciplinary Expert Panel who participated in a two-round RAND/University of California, Los Angeles (UCLA) modified Delphi process, with enhanced follow-up;
Development of a Boundary Guideline that takes a multi-vectorial approach to incorporate simultaneously a variety of gradients, including gradients of importance, relevance, and certainty, as appropriate to the construct being represented;
Specification and review of measures and approaches to measurement by stakeholders and experts; and
Testing and assessment of measure performance to the extent feasible given resources and available time.

The developer's feasibility work indicates that the time that the temperature is assessed, rather than simply the time that it is documented, is recorded in the medical record, generally an electronic medical record (EMR). This is a critical aspect of the validity of time data.

The underlying construct is core body temperature. Modern temperatures are valid and precise. The core body temperature is the highest of the accurate (legitimate) temperatures that may be obtained, so entities that report this measure will have aligned motivation to estimate temperatures that are as close to the core body temperature as possible. In one sense, the measure was designed with a compromise to pragmatism and can be thought of as having designed in a 0.5° "discount" in that the data suggest that optimal outcomes are obtained at 37.0° Celsius, rather than at the 36.5 in the measure (which is still far preferable to cooler). As noted above, data suggest that this 0.5° Celsius correction is at least adequate for population level use. Further, hypothermic infants should be managed clinically using core body temperature, so there is further clinical alignment for the use of a method that approximates core body temperature.

Data from pretesting supports various aspects of this measure. All data are from the New York State neonatal database. Data include reports from 20 Level 2 nurseries, 27 Level 3 nurseries, and 14 Regional Perinatal Centers that contributed 20 or more infants for the reporting year assessed. Data included all inborn infants from these hospitals with a birthweight of 400 to 2,499 grams whose admission temperature was 29° Celsius or higher (thus excluding potential data errors). Excluded were those with anencephaly or those who expired within 48 hours without receiving respiratory support beyond oxygen in the NICU. N=7,553. The number of infants ranged from 21 to 370 per hospital and 86.7% were admitted to Level 3 or higher hospitals. For this work, the first temperature on admission to a Level 2 or higher nursery for those admitted within 24 hours of birth was used.

In keeping with the categorical approach applied by the fourth measure in this set, the developer found that 1.9% of infants were less than or equal to 34.5 (cold), 9.6% above 34.5 but less than or equal to 35.5 (very cool), 48.0% above 35.5 but less than or equal to 36.5 (cool), 37.9% above 36.5 but less than or equal to 37.5 (euthermic or appropriately warm), and 2.6% above 37.5 (overly warm).

There were only 67 newborns that were transferred in from another facility. The distributions of temperatures were similar to the inborn infants, with the exception the transferred infants were slightly more likely to be euthermic.

Of the inborn infants, the temperatures ranged from 29.0 to 39.7. Refer to Table 2 in the original measure documentation. The median was 36.4, the mean was 36.3, and the standard deviation was 0.7 with an interquartile range of 0.80.

Only four infants arrived in the Level 2 or higher nurseries from the Emergency Department. One infant was euthermic, one was cool, and two were very cool. Nearly 1% were transferred from the Newborn Nursery, of which 48% were euthermic, 44% cool, and only 6% very cool. None were cold.

The developer did not have delivery location in the dataset and therefore classified neonates born by Caesarean section (C-section) or deliveries of multiple gestations as being born in the operating room (5,254) and the remainder were classified as being born in a labor and delivery room/birthing room (2,245). Of those born in the operating room (OR), 2% were cold, 11% were very cool, 72% were cool, and 35% were euthermic. Those born in the labor and delivery (L&D) suite were warmer with 2% cold, 7% very cool, 13% cool, 48% euthermic, and 45% too warm (p less than .0001). This suggests that the categorization of babies born in the OR (while imperfect) does identify a distinct population. The Expert Panel recommended that the developer report by site of delivery.

Temperatures varied by birthweight category (p less than.0001) considering those less than 1,000 grams, 1,000 to 1,499 grams, and 1,500 to 2,499 grams, as suggested by the Expert Panel. The percent cold was over 10% for those under 1,000 g (two-thirds of all cold babies from a group that was about 12% of all babies). These infants also were least likely to be euthermic; only 25% were so classified, compared to 34% of those in the intermediate weight category and 41% of the larger babies.

Using the categories defined in this measure, in hospital deaths were disproportionately represented among cooler babies. 2.6% of babies died before discharge: 24.5% of cold; 5.4% of very cool, 2.2% of cool babies, and 1.4% of euthermic babies died. Of the overly warm babies, 1.6% died. Only 20% of deaths came from euthermic infants.

Evidence for Extent of Measure Testing

CHIPRA Pediatric Quality Measures Program (PQMP) candidate measure submission form (CPCF): thermal condition of low birthweight neonates admitted to Level 2 or higher nurseries in the first 24 hours of life. Rockville (MD): Collaboration for Advancing Pediatric Quality Measures (CAPQuaM); 42 p.

State of Use of the Measure

State of Use

Current routine use

Current Use

not defined yet

Application of the Measure in its Current Use

Measurement Setting

Hospital Inpatient

Intensive Care Units

Other

Professionals Involved in Delivery of Health Services

not defined yet

Least Aggregated Level of Services Delivery Addressed

Clinical Practice or Public Health Sites

Statement of Acceptable Minimum Sample Size

Specified

Target Population Age

Newborn

Target Population Gender

Either male or female

National Strategy for Quality Improvement in Health Care

National Quality Strategy Priority

Institute of Medicine (IOM) National Health Care Quality Report Categories

IOM Care Need

Not within an IOM Care Need

IOM Domain

Not within an IOM Domain

Data Collection for the Measure

Case Finding Period

Unspecified

Denominator Sampling Frame

Patients associated with provider

Denominator (Index) Event or Characteristic

Clinical Condition

Institutionalization

Patient/Individual (Consumer) Characteristic

Denominator Time Window

not defined yet

Denominator Inclusions/Exclusions

Inclusions
Live-born neonates with birthweight of less than 2,500 grams (as identified from either the medical record or by International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] principal or other diagnosis codes) admitted to a Level 2 or higher nursery within 24 hours of birth

Note: Refer to the original measure documentation for codes.

Exclusions

Neonates who do not survive until the time limit of the measure (15 minutes after arrival to the Level 2 or higher nursery)
Neonates with anencephaly ICD-9-CM 740
Neonates not born in hospital/medical setting
Neonates with Comfort care (requires all of the features below): Died within 48 hours of birth AND received no respiratory support after arrival to the Level 2 or higher nursery other than blow by oxygen (i.e., did not receive continuous positive airway pressure [CPAP], intubation, or cardiopulmonary resuscitation [CPR] after arrival at Level 2 or higher nursery)
Neonates for whom the hospital provides documentation that at the time of arrival to the neonatal intensive-care unit (NICU) and before the temperature was taken the infant had been identified as meeting written institutional criteria for the initiation of therapeutic hypothermia and such therapy was begun or planned (optional exclusion)

Exclusions/Exceptions

not defined yet

Numerator Inclusions/Exclusions

Inclusions

Live-born neonates with a birthweight of less than 2,500 grams (as identified by International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] principal or other diagnosis codes) using the first temperature taken in a Level 2 or higher nursery

Note: The numerator has five comprehensive and mutually exclusive strata. Each is determined by the number of children whose qualifying temperature (usually the first temperature after arrival to the Level 2 or higher nursery) falls within the criteria for that stratum.

Stratum 1 "Cold": All neonates with temperatures less than or equal to 34.5° Celsius

Stratum 2 "Very Cool": All neonates with temperatures greater than 34.5° Celsius and less than or equal to 35.5° Celsius
Stratum 3 "Cool": All neonates with temperatures greater than 35.5° Celsius and less than or equal to 36.5° Celsius
Stratum 4 "Euthermic": All neonates with temperatures greater than 36.5° Celsius and less than or equal to 37.5° Celsius
Stratum 5: "Overly warm": All neonates with temperatures greater than 37.5° Celsius

Refer to the original measure documentation for administrative codes.

Exclusions
None

Numerator Search Strategy

Institutionalization

Data Source

Administrative clinical data

Electronic health/medical record

Paper medical record

Type of Health State

Physiologic Health State (Intermediate Outcome)

Instruments Used and/or Associated with the Measure

Unspecified

Computation of the Measure

Measure Specifies Disaggregation

Does not apply to this measure

Scoring

Frequency Distribution

Rate/Proportion

Interpretation of Score

Does not apply to this measure (i.e., there is no pre-defined preference for the measure score)

Allowance for Patient or Population Factors

not defined yet

Description of Allowance for Patient or Population Factors

General Data Elements for Stratification and Reporting:

- Birthweight
- 5 minute Apgar score
- Race/ethnicity
- Insurance type (public, commercial, none, other)
- Benefit category (Health Maintenance Organization [HMO], Preferred Provider Organization [PPO], Medicaid Primary Care Management Plan, Fee for Service, Other)
- Mother's state and county of residence and or ZIP code
- Medicaid or Children's Health Insurance Program (CHIP) benefit/qualifying category
- Born inside or outside of a medical facility
  - Location of birth
    - Operating room (e.g., for Cesarean section or double set up delivery)
    - Birthing room (birthing room is referring to a birthing or delivery room on a labor and delivery suite that is not an operating room)
    - Other
  - Location of birth unavailable:
    - If delivery occurred by Cesarean section then put location of birth as operating room
    - If this was a twin or multiple gestation delivery put location of birth as operating room
    - Otherwise put location of birth as birthing room/delivery room

Standard of Comparison

not defined yet

Identifying Information

Original Title

CAPQuaM PQMP PERINATAL IV: thermal condition of low birthweight neonates admitted to Level 2 or higher nurseries in the first 24 hours of life.

Measure Collection Name

Inpatient Perinatal Care

Submitter

Collaboration for Advancing Pediatric Quality Measures - Health Care Quality Collaboration

Developer

Collaboration for Advancing Pediatric Quality Measures - Health Care Quality Collaboration

Funding Source(s)

Unspecified

Composition of the Group that Developed the Measure

Unspecified

Financial Disclosures/Other Potential Conflicts of Interest

Unspecified

Adaptation

This measure was not adapted from another source.

Date of Most Current Version in NQMC

2014 Aug

Measure Maintenance

Unspecified

Date of Next Anticipated Revision

Unspecified

Measure Status

This is the current release of the measure.

Measure Availability

Source available from the Collaboration for the Advancement of Pediatric Quality Measures (CAPQuaM) Web site .

For more information, contact Dr. Lawrence Kleinman, Director of Collaboration for Advancing Pediatric Quality Measures (CAPQuaM) at the Icahn School of Medicine at Mount Sinai, Department of Population Health and Policy at 1 Gustave L. Levy Place, Box 1077, New York, NY 10029; Phone: 212-659-9567; E-mail: Lawrence.Kleinman@mountsinai.org; Web site: www.capquam.org .

NQMC Status

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Copyright Statement

Production

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